UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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| IN RE: ZIMMER M/L TAPER HIP PROSTHESIS OR M/L TAPER HIP PROSTHESIS WITH KINECTIV TECHNOLOGY AND VERSYS FEMORAL HEAD PRODUCTS LIABILITY LITIGATION. | : | MDL NO. 2859<br><br>18-MD-2859 (PAC)<br>18-MC-2859 (PAC)<br>19-CV-699 (PAC) |
| TAMMA NUTTING,<br>*Plaintiff,*<br><br>*-against-*<br><br>ZIMMER, INC. et al.,<br><br>*Defendants.* | : | **OPINION & ORDER** |
| *This Document Relates to All Cases* | : | |

Defendants Zimmer, Inc. and Zimmer US, Inc. (collectively "Zimmer")[1] manufacture hip prostheses, among other medical devices. The Plaintiffs in this multidistrict litigation ("MDL") are individuals who received Zimmer's VerSys femoral head combined with either the Zimmer M/L Taper or the Zimmer M/L Taper with Kinectiv Technology during total hip replacement ("THR") surgery. The Kinectiv is an additional neck piece that joins the taper stem to the femoral head, and it allows surgeons more options for customization as opposed to the single-piece M/L Taper stem. Plaintiffs allege that when these products are combined, they are prone to micromotion between components, which causes metal release and corrosion. *See* Long Form

[1] Plaintiff Tamma Nutting's original short form complaint named Zimmer Biomet Holdings, Inc. as a defendant, too. However, Nutting subsequently dismissed Zimmer Biomet Holdings as a party to this action. Stipulation of Dismissal 1–2, ECF No. 413. This dismissal mooted Zimmer's additional motion for summary judgment on the issue of whether Zimmer Biomet Holdings is a proper defendant to this action. ECF No. 366.

Unless otherwise indicated, all ECF citations are to the master docket, number 18-md-2859.

Compl. ¶¶ 125, 155–56, ECF No. 71–1. In turn, Plaintiffs allege, the metal release caused them tissue necrosis and pain (among other injuries), and necessitated revision surgeries to replace the products. *Id.* at ¶¶ 156, 168, 185. Plaintiffs contend that corrosion occurred at the taper junction of the components highlighted in blue in the image below:


Zimmer's Mem. Supp. Mot. Exclude Test. of Truman 3, ECF No. 375.

On December 16, 2020, the Court ruled that Plaintiff Tamma Nutting's case against Zimmer (No. 19-cv-699) would proceed as the first bellwether trial in this MDL. Order No. 52 at 1, ECF No. 320. Nutting's trial is scheduled to begin on September 28, 2021. Eighth Amend. Schedule at 3, ECF No. 408. Nutting has had three hip surgeries: (1) a right THR on March 15, 2011; (2) a left THR on June 18, 2012;[2] and (3) a revision surgery on her right hip on December 14, 2017. Pls.' Local Civil Rule 56.1 Statement of Facts 2–3, ECF No. 434 ("Pls.' SOF").[3] This litigation concerns Nutting's right THR.

[2] Nutting received a ceramic femoral head and an M/L Taper stem during her left THR surgery. Pls.' Local Civil Rule 56.1 Statement of Facts 2–3, ECF No. 434.

[3] Plaintiffs' Local Civil Rule 56.1 statement of facts includes both Zimmer's statements of allegedly undisputed facts and Plaintiffs' objections and responses to those statements, as well as Plaintiffs' additional statements of allegedly undisputed facts.

In advance of trial, Zimmer moves to exclude the testimony of three of Plaintiffs' expert witnesses, and Plaintiffs move to exclude the testimony of three of Zimmer's expert witnesses, pursuant to Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993). ECF Nos. 371, 374, 379, 383, 386, 388. Additionally, Zimmer moves for summary judgment on all of Nutting's remaining claims. ECF No. 390. Only Zimmer's motion to exclude the testimony of Mari Truman need be resolved for the Court to rule on Zimmer's summary judgment motion. Therefore, the Court will rule only on Zimmer's motion to exclude Truman's testimony and Zimmer's motion for summary judgment, because the grant of summary judgment moots the other motions to exclude expert testimony. *See In re Zimmer NexGen Knee Implant Prods. Liab. Litig.*, 218 F. Supp. 3d 700, 704 (N.D. Ill. 2016), *aff'd*, 884 F.3d 746 (7th Cir. 2018); *In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig. (No. II)*, 982 F.3d 113, 122 (2d Cir. 2020).

The Court finds that Truman's proffered design defect opinions are unreliable and unhelpful, and therefore must be excluded under *Daubert* and Rule 702. With Truman's testimony excluded, Plaintiffs have no evidence that the Zimmer products implanted in Nutting during her right THR surgery contained a specific, identifiable defect. Plaintiffs cannot proceed to trial with circumstantial evidence under a malfunction theory of defect, because the products at issue are not of a type such that the corrosion and injury Nutting allegedly experienced would not be expected absent a defect attributable to Zimmer. Thus, the Court grants Zimmer summary judgment on Nutting's design defect claim. The Court also grants Zimmer summary judgment on Nutting's failure to warn claim, because Plaintiffs have not produced evidence sufficient for a reasonable jury to find that any alleged failure to warn was the proximate cause of Nutting's injuries. Finally, the Court grants Zimmer summary judgment on Nutting's negligence claim,

because under Idaho law, a products liability negligence claim must satisfy the same elements required to prove a strict liability defect or failure to warn claim; as Nutting has failed to establish a genuine issue regarding the existence of a defect or that a failure to warn proximately caused her injuries, summary judgment on her negligence claim necessarily follows.

## BACKGROUND

During Nutting's right THR surgery on March 15, 2011, Dr. Mark Meier implanted a Zimmer 36mm +0 offset[4] cobalt-chrome VerSys Femoral Head (the "+0 VerSys head") and a Zimmer 12/14 M/L Taper Kinectiv Stem and Neck (the "Kinectiv," and together with the +0 VerSys head, "Nutting's Device").[5] Pls.' SOF 5–6. Following her right THR, Nutting's pain improved, and she did not experience any problems with her right hip for the next six years. *Id.* at 14.

In mid-2017, however, Nutting complained to her primary care physician about pain in her right hip and groin. *Id.* at 16. In August 2017, Dr. Meier, Nutting's implanting surgeon, ordered a series of tests to determine the cause of her pain. *Id.* at 17. Upon reviewing Nutting's blood test results, Dr. Meier found that Nutting's cobalt levels were "above the reference range," "abnormal," and "high." *Id.* at 17–18 (quoting Decl. of Peter Meyer Supp. Mot. Summ. J. Ex. B, Meier Dep. Tr. 103:3–104:5, ECF No. 393–2 ("Meier Dep. Tr.")). He noted that the other tests did not show any evidence of infection, and concluded that Nutting was experiencing "right hip

[4] Offset "increases the distance between: (1) the location where the femoral head and the 12/14 Taper meet; and (2) the location where the body weight passes through the femoral head, which increases the moment arm and the potential for fretting and corrosion at the taper junction." Zimmer's Mem. Supp. Mot. Exclude Test. of Truman 3, ECF No. 375 (citing Decl. of Peter Meyer Supp. Mot. Exclude Test. of Truman Ex. B, Truman Dep. Tr. 129:17–131:2, ECF No. 376–2).

[5] Plaintiffs point out that Dr. Meier also implanted other items (bone screws, a shell, and a liner), but Plaintiffs do not allege that those items are defective, individually or in combination. Pls.' SOF 5–6.

pain, most likely secondary to metallosis and possible adverse local tissue reaction." *Id.* at 18 (quoting Meier Dep. Tr. 245:18–23). Dr. Meier defines "metallosis" as "[b]asically elevated cobalt levels," and "adverse local tissue reaction" as "an inflammatory response" that involves the body's attempt to remove cobalt from the hip area. *Id.* at 18–19 (quoting Meier Dep. Tr. 109:8–13, 245:24–25, 246:1–6).

Dr. Meier determined that it was necessary to revise Nutting's right hip—that is, to reopen her hip and replace her Device. *Id.* 20–21. On December 14, 2017, Dr. Meier performed Nutting's revision surgery. *Id.* at 21. Inside Nutting's right hip, Dr. Meier noticed inflammation as well as tissue that he believed was necrotic (dead), which he debrided (removed). *Id.* at 24–26. Dr. Meier also observed a black layer within the bore of Nutting's +0 VerSys head, which he believed was corrosion. *Id.* at 25–26. Dr. Meier testified that these intraoperative observations were consistent with adverse local tissue reaction. *Id.* at 19 (citing Meier Dep. Tr. 109:23–112:22). Dr. Meier replaced Nutting's +0 VerSys head with a ceramic head, but left the Kinectiv components in place. *Id.* at 26. Nutting's +0 VerSys head was not preserved for testing or examination, nor were any tissue samples sent to pathology for analysis. *Id.* at 27–28.

Pathology involves microscopic examination of tissue. *See id.* Dr. Meier agreed that without pathology, he could not definitively determine that the tissue he debrided from Nutting was actually necrotic, although as a surgeon, he is able to determine from gross examination whether tissue looks dead. *Id.* at 28–29. Dr. Meier stated that Nutting's need for revision was "the result of the implant system," the "area where the trunnion was on the cobalt head," and that the corrosion was caused by Nutting's "cobalt chrome head." *Id.* at 21–22 (quoting Meier Dep. Tr. 117:15–118:14). But Dr. Meier acknowledged that corrosion can be present in well-functioning hip implants, too. *Id.* at 33.

Pursuant to FDA regulations (21 C.F.R. § 801 *et seq.*), Zimmer supplies surgeons with instructions and warnings regarding its products in "a package insert that contains Instructions for Use (IFU)." *Id.* at 82–83. The +0 VerSys head and the Kinectiv each has its own IFU, though they have identical lists of adverse effects. *See id.* at 83–86; Decl. of Peter Meyer Supp. Mot. Summ. J. Ex. L, Kinectiv IFU, ECF No. 393–12; Decl. of Peter Meyer Supp. Mot. Summ. J. Ex. M, VerSys IFU, ECF No. 393–13. Plaintiffs dispute whether these IFUs were included with Nutting's Device, but do not point to evidence that they were not included. Pls.' SOF 84.

The IFUs for Nutting's Device list wear, metal sensitivity, inflammatory reactions, and corrosion of metal implants as "adverse effects" of the components. Pls.' SOF 84–86. At his deposition, Dr. Meier initially stated that he reviewed the IFUs. *Id.* at 89–90. But when Zimmer later presented him with the IFUs, Dr. Meier retracted his testimony and said he had not read them prior to his deposition. *Id.* at 91–92. Dr. Meier repeated that he did not review the package inserts. *Id.*

Zimmer also provides surgical technique manuals for some of its devices, including the Kinectiv. *Id.* at 92; *see also* Decl. of Peter Meyer Supp. Mot. Summ. J. Ex. O, Kinectiv Surgical Technique, ECF No. 393–15. The Kinectiv Surgical Technique instructs surgeons to ensure that the neck taper is clean and dry, "[s]ecure both tapers by striking the femoral head once," and "[t]est the security of the head and neck fixation by trying to remove the head by hand." Pls.' SOF 92–93 (quoting Decl. of Peter Meyer Supp. Mot. Summ. J. Ex. O, Kinectiv Surgical Technique at 14). Dr. Meier testified that it is his practice to impact the head two to three times, and that he learned this practice as a resident, rather than from the Kinectiv Surgical Technique. *Id.* at 94–96. Dr. Meier tests the security of the trunnion engagement by "tak[ing] something and try[ing] to knock [the head] the other way to see if it pops off." *Id.* at 97–98 (quoting Meier Dep.

Tr. 100:18–21).[6] Dr. Meier testified that a Zimmer sales representative was present in the operating room for Nutting's surgery, and Dr. Meier was never told that his surgical technique is improper or deficient. Pls.' SOF 48, 110.[7]

Nutting never communicated with Zimmer, nor had she even heard of Zimmer, prior to her right THR surgery. *Id.* at 105–106. Nutting did not read or rely upon Zimmer's documents "in making her decision to have the Zimmer Device implanted," instead, she received information about the Device and the surgery from Dr. Meier, whose medical judgment she trusted and relied upon. Pls.' SOF 104–106.

On December 6, 2018, Nutting filed suit against Zimmer in the United States District Court for the District of Idaho, seeking to recover for her injuries. Zimmer's Mem. Supp. Summ. J. 4, ECF No. 392. Her case was subsequently transferred to this MDL, and on March 21, 2019, Nutting filed her short form complaint with this Court. *Id.* Nutting's short form complaint contained 12 counts.[8] She has since voluntarily dismissed nine of those counts. Stipulation of Dismissal 1–2, ECF No. 413; Stipulation of Dismissal 1–2, ECF No. 444.

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[6] Defendants represent this as Dr. Meier's method of testing head-neck fixation. Pls.' SOF 97–98. Plaintiffs object, stating that Dr. Meier uses this method to test the engagement of head and *stem*, not head and neck. *Id.* This appears to be a distinction without a difference, as the head connects to the stem through the neck trunnion, regardless of whether the implant uses a single-piece stem or a two-piece stem.

[7] These are additional facts asserted by Plaintiffs, who get the last word with Rule 56.1 statements. However, because this testimony comes directly from Dr. Meier's deposition transcript, any dispute as to whether Dr. Meier so testified would not be genuine.

[8] Negligence (Count I); negligence per se (Count II); strict products liability–defective design (Count III); strict products liability–manufacturing defect (Count IV); strict products liability–failure to warn (Count V); breach of express warranty (Count VI); breach of warranty as to merchantability (Count VII); breach of implied warranties (Count VIII); violation of consumer protection laws (Count IX); negligent misrepresentation (Count X); fraudulent concealment (Count XI); and unjust enrichment (Count XII). Nutting Short Form Compl. 5, No. 19-cv-699, ECF No. 22.

Nutting's remaining causes of action are: negligence (Count I); strict products liability–defective design (Count III); and strict products liability–failure to warn (Count V).

Nutting is a citizen of Idaho, and Dr. Meier performed her right THR surgery in Idaho. Nutting Short Form Compl. 1–2, No. 19-cv-699, ECF No. 22. The parties agree that Idaho law governs Nutting's claims. *See* Zimmer's Mem. Supp. Summ. J. 5–6; Pls.' Opp'n Summ. J. 11–12, ECF No. 433.

## DISCUSSION

### I. Idaho Substantive Law

Idaho recognizes "three main categories of strict liability in product liability cases—manufacturing flaws, design defects, and failure to warn." *Grunig v. Johnson & Johnson*, No. 18-cv-00111, 2019 WL 6868956, at *6 (D. Idaho Dec. 16, 2019) (citing *Toner v. Lederle Laboratories*, 732 P.2d 297, 306 (Idaho 1987); *Mortensen v. Chevron Chem. Co.*, 693 P.2d 1038, 1041 (Idaho 1984)). "Regardless of the theory under which recovery is sought in a products liability action, a plaintiff must establish that the injury is causally related to defendant's act or omission." *Green v. W.L. Gore & Assocs.*, No. 19-cv-00022-DCN, 2020 WL 5658352, at *2 (D. Idaho Sept. 23, 2020) (quoting *Watson v. Navistar Int'l Transp. Corp.*, 827 P.2d 656, 674 (Idaho 1992)). Nutting brings product liability claims in strict liability and negligence for design defect and failure to warn.

To prevail on a claim of design defect, a plaintiff must prove that "(1) [s]he was injured by the product; (2) the injury was the result of a defective or unsafe product; and (3) the defect existed when the product left the control of the manufacturer." *Black v. DJO Glob., Inc.*, 488 P.3d 1283, 1287 (Idaho June 9, 2021). These elements are the same regardless of whether the claim is couched in terms of strict liability or negligence. *Grunig*, 2019 WL 6868956, at *7;

*Glenn v. B & R Plastics, Inc.*, 326 F. Supp. 3d 1044, 1071 (D. Idaho 2018). A product is defective if it "does not meet the reasonable expectations of the ordinary consumer as to its safety." *Black*, 488 P.3d at 1287 (quoting *Farmer v. Int'l Harvester Co.*, 553 P.2d 1306, 1311 (Idaho 1976)). A manufacturer must design its product "so as to eliminate unreasonable risks of foreseeable injuries." *Green*, 2020 WL 5658352, at *3 (quoting *Puckett v. Oakfabco, Inc.*, 979 P.2d 1174, 1179 (Idaho 1998)). "Similarly, a product is defective when it exposes a user or bystander to an unreasonable risk of physical injury." *Id.* (citing *Puckett*, 979 P.2d at 1179).

"[T]here are two pathways to proving a product is defective: (1) direct evidence of an identifiable, specific defect; or (2) evidence of a malfunction of the product and the absence of evidence of abnormal use and the absence of evidence of reasonable secondary causes which would eliminate liability of the defendant." *Black*, 488 P.3d at 1287 (citing *Farmer*, 553 P.2d at 1311). The Idaho Supreme Court calls this latter pathway, which relies upon circumstantial evidence, the "malfunction theory." *Id.* The malfunction theory is useful where the plaintiff cannot identify a specific defect, or where the product is no longer available for examination. *Id.* at 1288.

To demonstrate that a product malfunctioned, "the product at issue must be of a type which permits a jury to infer that an injury would not have occurred had there not been a defect attributable to the manufacturer." *Id.* (citing *Farmer*, 553 P.2d at 1313). If the product is not of such a type, then the plaintiff cannot demonstrate a malfunction, and the court "need not address the issues of abnormal use and reasonable secondary causes." *Id.*

Failure to warn is also "a potential basis for recovery in products liability actions—whether alleged under strict liability or negligence." *Grunig*, 2019 WL 6868956, at *10 (citing *Puckett*, 132 P.2d at 1181). "A product is defective under the failure to warn theory when 'the

defendant has reason to anticipate that danger may result from the particular use' of the product 'and fails to give adequate warnings of such danger.'" *Id.* (citing *Puckett*, 132 P.2d at 1181). As with a design defect claim, the plaintiff "'must establish that the failure to warn was the proximate cause' of his injuries." *Id.* (citing *Hepburn v. Boston Sci. Corp.*, No. 17-cv-00530-DCN, 2018 WL 2275219, at *6 (D. Idaho May 17, 2018)). The plaintiff also "must prove the absence of evidence of abnormal use and the absence of evidence of reasonable secondary causes." *Glenn*, 326 F. Supp. 3d at 1061–62 (collecting cases).

## II. Zimmer's Motion to Exclude Mari Truman's Testimony

### A. Standard for Admissibility of Expert Testimony

"A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702; *Daubert*, 509 U.S. at 597.

District courts act as the gatekeepers of evidence, determining whether proffered expert testimony is sufficiently reliable and relevant that it should reach the jury. *In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig (No. II)*, 982 F.3d at 122–23. This "'gatekeeping obligation' under *Daubert* applies to all expert testimony." *Twelve Sixty LLC v. Extreme Music Libr. Ltd.*, No. 17-cv-1479, 2020 WL 274970, at *7 (S.D.N.Y. May 26, 2020) (quoting *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 147 (1999)). "The proponent of expert testimony carries the burden of establishing its admissibility by a preponderance of the evidence . . . ."

*Choi v. Tower Rsch. Cap. LLC*, 2 F.4th 10, 20 & n.52 (2d Cir. 2021) (citing *United States v. Williams*, 506 F.3d 151, 160 (2d Cir. 2007)). The Court of Appeals applies "a highly deferential abuse of discretion standard" to the "district court's decision to admit or exclude expert testimony." *In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig (No. II)*, 982 F.3d at 122 (citing *Zuchowicz v. United States*, 140 F.3d 381, 386 (2d Cir. 1998)).

"[A]n expert's methodology must be reliable at every step of the way, and '[i]n deciding whether a step in an expert's analysis is unreliable, the district court should undertake a *rigorous examination* of the facts on which the expert relies, the method by which the expert draws an opinion from those facts, and how the expert applies the facts and methods to the case at hand.'" *Id.* at 123 (citing *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 267 (2d Cir. 2002)) (first alteration added; further alterations in original).

**B. Mari Truman's Proposed Expert Testimony**

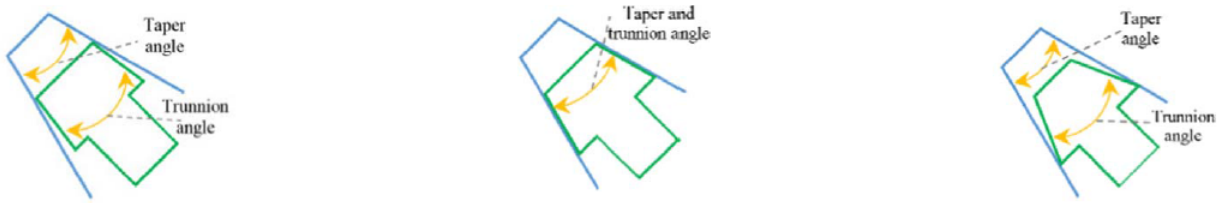
Mari Truman is a biomedical engineer who holds 12 patents for orthopedic devices and has 40 years' experience in biomechanics and orthopedics, including work designing and evaluating orthopedic devices. Decl. of Peter Meyer Supp. Mot. Seal Ex. B, Truman's Unredacted Expert Report 1, ECF No. 370–2 ("Truman Report"). Plaintiffs retained Truman to "determine if the Zimmer M/L Taper hip stems, [and] M/L Taper hip stems with Kinectiv technology, mated with VerSys CoCr [(cobalt-chromium)] heads, were defectively designed in a manner that caused the premature failures in plaintiffs due to head-neck interface fretting corrosion and ensuing local tissue reactions and pain." *Id.* at 3. Zimmer does not challenge Truman's qualifications in biomechanical engineering, but instead argues that her opinions lack supporting data and should be excluded as unreliable. Zimmer's Mem. Supp. Mot. Exclude Test. of Truman 8.

Truman plans to testify that Nutting's Device is defective because Zimmer designed an intentional five-minute taper angle mismatch between the bore of the +0 VerSys head and the trunnion of the Kinectiv neck, which "has a high likelihood of MACC [(machine-assisted crevice corrosion)]."[9] *See* Truman Report 7–8, 13; *see also* Decl. of Peter Meyer Supp. Mot. Exclude Test. of Truman Ex. B, Truman Dep. Tr. 183:21–184:24; 197:18–22; 312:18–23, ECF No. 376–2 ("Truman Dep. Tr."). The "mismatch" is the difference between the angles of the components, which affects how the components will fit together at the taper junction where the head and neck trunnion join when the surgeon impacts them together. Truman Report 30, 32–33; Truman Dep. Tr. 176:6–177:23; Pls.' Unredacted Opp'n Mot. Exclude Test. of Truman 3, ECF No. 430–2.

[9] MACC is a problem because it "produces cobalt, metal ions, fretting particulates and corrosive debris that have been associated with adverse local tissue reactions (ALTR) or more specifically adverse reaction to metal debris (ARMD)," which can cause pain, tissue damage, and the need for revision surgery. Truman Report 4.

Because the bore of the head has a certain angle, and the trunnion of the neck has a certain angle, one of three things will happen when the components are joined together: (1) the angles are mismatched, and the neck trunnion contacts the inside of the head bore near the top of the trunnion, which is called a "tip lock"; (2) the angles are matched, and the trunnion contacts the interior of the bore through the length of the neck trunnion; or (3) the angles are mismatched, and the neck trunnion contacts the inside of the head bore near the base of the neck trunnion, which is called a "base lock." All three are illustrated in the image below:

| Tip locked | Matched | Base locked |
|---|---|---|




Pls.' Unredacted Opp'n Mot. Exclude Test. of Truman 4. Truman explains that it is impossible to manufacture every part to have a perfect fit every time, so manufacturers prescribe tolerance bands—essentially, defining the amount by which a component's angle may deviate from the intended target (the "nominal") and still be considered to fall within manufacturing specifications. *Id.* at 3 & nn. 1, 3; Truman Report 7–8, 71; Truman Dep. Tr. 106:3–107:14, 176:6–177:23; Zimmer's Mem. Supp. Mot. Exclude Test. of Truman 12.

With the +0 VerSys head and Kinectiv neck, the taper angles are measured in degrees and fractions of degrees. "[O]ne minute is equal to 1/60th of one degree, and one second is equal to 1/60th of one minute, or 1/3600th of a single degree." Zimmer's Mem. Supp. Mot. Exclude Test. of Truman 12. As mentioned, Zimmer's target mismatch between the +0 VerSys head and the Kinectiv neck trunnion is five minutes. Zimmer's tolerance band for each component is plus

or minus two minutes, 30 seconds; thus, assuming that the components fall within specification, the maximum possible mismatch between the +0 VerSys head and the Kinectiv neck trunnion is 10 minutes. *Id.* at 12; Truman Report 7–8; Pls.' Unredacted Opp'n Mot. Exclude Test. of Truman 3.

Truman opines that (1) increased mismatch can increase micromotion between the surface of the trunnion and the surface of the head bore, leading to "fretting" (the breakdown of metal) and MACC (Truman Report 13; Pls.' Unredacted Opp'n Mot. Exclude Test. of Truman 8); (2) mismatches greater than four minutes, 30 seconds are in the range sufficient to cause micromotion and fretting, and mismatches greater than six minutes combined with a base lock can cause "exaggerated and progressive fretting" compared to a tip lock (Truman Report 13); (3) when combined with a mismatch, a base lock can cause more fretting than a tip lock, and rough surface topography could increase fretting (Truman Report 33, 71, 74–75; Truman Dep. Tr. 179:24–180:4, 193:22–197:22, 311:21–312:23); and (4) Nutting's Device is designed to have a five minute mismatch and a base lock with a rough surface topography, so her Device is defective (Truman Report 8, 13, 74–75; Truman Dep. Tr. 86:4–88:14, 179:6–15). Truman further opines that Nutting's Device is defective because "there were safer[,] more durable design alternatives for the head/neck junction including" using a ceramic head or a "ceramitized" titanium alloy and reducing the mismatch tolerance. Truman Report 13–14.[10]

[10] Truman clarified that she does not intend to offer opinions regarding: (1) what caused the corrosion in Nutting's Device; (2) what the medical cause of Nutting's injuries was; or (3) Zimmer's warnings or surgical technique for Nutting's Device. *See* Zimmer's Mem. Supp. Exclude Test. of Truman 34 (quoting Truman Dep. Tr. 39:9–10, 81:9–24, 316:23–318:13). Plaintiffs do not oppose Zimmer's motion to exclude any of those opinions. *See generally* Pls.' Unredacted Opp'n Mot. Exclude Test. of Truman. That motion is moot, however, in light of the Court's other rulings in this order.

**C. Mari Truman's Design Defect Opinions Are Inadmissible**

The core problem with Truman's proposed testimony is that there is too large a gap between the data she relies upon and the conclusions she reaches. Truman reviewed the production records for the lot from which Nutting's Device came,[11] and found that the components have a combined mismatch ranging from approximately three minutes, twenty seconds to seven minutes.[12] Truman Dep. Tr. 83:17–85:15. Truman testified that Nutting's Device could contain a mismatch anywhere in that range; that most of the components were "all hovering around nominal specifications of 5 minutes"; and that the chance Nutting's Device had more than six minutes of mismatch is "[r]oughly 1 in 50, 1 in 52." *Id.* at 85:20–87:14, 313:1–14. From this, Truman concludes that Nutting's Device was defective, because it contained some amount of mismatch which resulted in base locking. *Id.* at 88:3–16. But this chain of reasoning assumes that the amount of mismatch in Nutting's Device was sufficient to cause her injuries, without explaining how much mismatch is necessary for clinically significant corrosion and adverse local tissue reaction to occur. Thus, Truman's mismatch defect opinion is inadmissible. *Boucher v. U.S. Suzuki Motor Corp.*, 73 F.3d 18, 22 (2d Cir. 1996) ("Admission of expert testimony based on speculative assumptions is an abuse of discretion.").

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[11] Zimmer does not serialize its production, so there is no way to tell which parts Nutting received from that lot. Further, Nutting's Device was not preserved after her revision surgery, so Truman did not have it available to conduct her own measurements. Truman Dep. Tr. 88:17–25, 90:1–6, 313:1–14.

[12] Zimmer objects that Truman did not disclose in her expert report (1) her method of tabulating the mismatch ranges in Nutting's production lot and (2) her conclusions as to what those ranges were. Zimmer's Reply Supp. Mot. Exclude Test. of Truman 8–9, ECF No. 449. Truman did, however, disclose that she reviewed the production records, and her tabulation method appears to be little more than grade school arithmetic; additionally, Zimmer had an opportunity to examine Truman on this issue during her deposition. Truman Rep. 85; Truman Dep. Tr. 83:16–87:4. Accordingly, Truman's disclosure was adequate, and her method of tabulation is not so vague that the Court must exclude it. *See* Fed. R. Civ. P. 26(2)(B); *Twelve Sixty LLC v. Extreme Music Libr. Ltd.*, No. 17-cv-1479, 2020 WL 2749708, at *10 (S.D.N.Y. May 26, 2020).

Truman admitted that it is not feasible to machine a perfect fit every time, so there will almost always be some amount of mismatch. Truman Dep. Tr. 176:10–177:19; Truman Report 71. Truman agrees that not all cobalt-chromium femoral heads are defective, not all modular neck devices are defective, and not all metal-on-polyethylene hip systems are defective. Truman Dep. Tr. 48:4–6, 110:5–111:17, 227:22–228:1. She further explained that the presence of corrosion does not mean a product is defective: "Q: Okay. All right. Based on all the factors that we just discussed, you agree that the fact that corrosion occurs at a head-neck taper junction in a hip device does not mean that the device had to have been defective or unreasonably dangerous? A: Correct. I mean, all of the tapers corrode to a certain extent." *Id.* at 169:8–15. Truman agreed that all modular hip devices are susceptible to corrosion at the head-neck taper junction, not all hip implant corrosion is clinically significant, and all metal implants in the human body will corrode to some degree as long as they are touching fluid. *Id.* at 169:20–170:5. Truman explained that "[s]ince fluid is always present around the hip joint, the way to minimize fretting and crevice corrosion is the restriction of the relative motion at the taper interface." Truman Report 5. Given her concession that a mismatch is not always defective, Truman's conclusion that "[t]he design of the Zimmer M/L Taper/VerSys CoCr head hip implant combination is defective in that it intentionally creates a misfit that has a high likelihood of MACC" is unsupported where she cannot specify what level of mismatch creates that "high likelihood of MACC." Truman Report 8.

In support of Truman's mismatch defect opinion, Plaintiffs cite to testing that Zimmer performed comparing a +7 offset femoral head with an M/L Taper to the Avenir-Durasul product combination. Pls.' Unredacted Opp'n Mot. Exclude Test. of Truman 8–12; Zimmer's Reply Supp. Mot. Exclude Test. of Truman 3–4, ECF No. 449; Decl. of Kelly McNabb Opp'n Mot.

Exclude Test. of Truman Ex. F, Zimmer Presentation ZIM-SDNY MDL00420417 at 29, ECF No. 437–6. But it is Truman's opinions that the Court must assess, not Plaintiffs' counsel's arguments. *In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 407 (S.D.N.Y. 2005). Truman does not explain whether or how the +7 head and the +0 head are substantially similar such that the testing of a +7 head provides reliable information about the predicted performance of a +0 head, like the one Nutting received. *See generally* Truman Report 61–68 (discussing Zimmer's Fretted and Corroded Taper Solutions ("FACTS") testing); *cf. Borsack v. Ford Motor Co.*, No. 04 Civ. 3255, 2007 WL 2142070, at *6 (S.D.N.Y. July 26, 2007) (denying *Daubert* motion where expert conducted testing on a substantially similar product and explained how the products are similar). In fact, Truman suggests that a +7 head is *not* substantially similar to a +0 head, because an increased head offset is an important factor affecting micromotion, fretting, and MACC. *See* Truman Report 4, 34, 42 (discussing research finding that micromotion increases with additional head offset, and linking "increased offset and taper interface fretting and corrosion"), 57 (criticizing Zimmer's testing of a +0 ceramic head on a Kinectiv plug against a six-degree stem with a long offset head as "not compar[ing] similar devices, offsets, junction locations, or metal materials"); Truman Dep. Tr. 130:16–131:25 (agreeing that femoral head offset has "been shown to be one of the most important factors that affect" MACC, stating: "the higher the offset, the higher the risk"), 135:1–4 (agreeing that "corrosion performance will be best when you have a plus-zero offset femoral head"); 198:1–6 (agreeing that offset could "affect level at which mismatch becomes problematic").

Truman does not adequately explain her basis for crediting studies that examined different products from different companies over the contrary evidence provided by Zimmer's

testing of its own, similar products. For example, Truman cites a study by Ashkanfar et al,[13] which tested DePuy products and found that increased taper mismatch corresponded with increased fretting wear and recommended that head-neck junctions maintain a taper mismatch below six minutes. Truman Report 8, 71; Truman Dep. Tr. 199:21–206:20. But Truman noted that the Ashkanfar study did not evaluate corrosion effects, the "finite element" test they ran has limited usefulness, and to know how much mismatch is appropriate, one must test the actual design specifications of a given device. Truman Report 71; Truman Dep. Tr. 201:4–208:22. Truman admitted that she cannot cite to any testing showing either that the 12/14 Taper with a +0 VerSys head performs unacceptably when it comes to corrosion, or that the Avenir stem (which she contends is a safer alternative) performs better than the 12/14 Taper with a +0 head. Zimmer's Mem. Supp. Mot. Exclude Test. of Truman 4–5 (citing Truman Dep. Tr. 273:13–20, 303:4–9). Without testing, Truman agreed that she "can't really say where a mismatch becomes a problem for any particular design." Truman Dep. Tr. 202:1–20; *see also id.* at 208:9–22.

Truman contends that Zimmer should have conducted more testing to determine where the mismatch becomes a problem. *Id.* at 202:4–20, 217:2–19; *see also* Truman Report at 57–58. Setting aside that this contention assumes the conclusion[14] (that there is a level at which taper mismatch poses an unreasonable risk of MACC) and shifts the burden to Zimmer to *disprove* a defect, this opinion is not helpful to the jury. "Rule 702's 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility." *In re Rezulin*

[13] Ashkanfar et al (2017): A large taper mismatch is one of the key factors behind high wear rates and failure at the taper junction of total hip replacements: A finite element wear analysis (Truman Report 86, 97).

[14] *See In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 430 (S.D.N.Y. 2016) ("This exercise does not seem to have involved any scientific methodology, but rather consisted of reverse-engineering a theory to fit the desired outcome.").

*Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 540 (S.D.N.Y. 2004) (quoting *Daubert*, 509 U.S. at 591). Truman's opinion that Zimmer should have conducted additional testing lacks that scientific connection, because Truman does not explain the costs and benefits so that the factfinder could determine whether additional testing would be reasonable or unreasonable. *See Toner*, 732 P.2d at 301–02; *see also id.* at 310 n.11 ("[B]alancing risk against utility tests whether the conduct was unreasonable and thus a breach of duty."). In other words, simply asserting that Zimmer should have done more testing does not help the jury determine whether Zimmer acted reasonably.

When cross-examined on the testing that Zimmer did perform on the +0 VerSys head with a 12/14 titanium trunnion, Truman agreed (with qualifications)[15] that the results suggested acceptable performance, with "very tiny" mass loss. Truman Dep. Tr. 269:25–271:24. Truman said she would like to see the test performed with a full Kinectiv neck construct rather than a plug trunnion, but acknowledged that although full construct testing is an option, no industry standard requires it. *Id.* at 270:15–273:12; 293:5–9, 300:9–16. When Zimmer showed Truman the test results for the CLS Brevius, which was tested as a full construct (and which "uses the same Kinectiv neck, the same stem bore geometry, [and] the same VerSys head" as Nutting's Device), Truman agreed[16] that the testing showed mass loss of "about one" milligram, which Truman deemed "low enough." *Id.* at 274:21–275:24, 302:1–303:3. Truman (1) does not have any data showing that Nutting's Device performs unacceptably from a corrosion standpoint; (2) cannot identify the threshold at which taper mismatch becomes problematic in Nutting's Device;

[15] Truman criticized the test's small sample size and said she would like to see the test repeated with current techniques for measuring the volume loss. Truman Dep. Tr. 270:8–273:12.

[16] Truman again noted the test's small sample size, along with the amount of standard deviation, and said she would "want to make sure it was truly the Kinectiv without a change in the taper." Truman Dep. Tr. 302:11–22.

and (3) agrees that the testing that *does* exist suggests that Nutting's Device performs acceptably. In light of these admissions, Truman's opinion that the taper mismatch in Nutting's Device is a design defect because it has a high likelihood of MACC is too speculative to survive scrutiny under *Daubert*.

Truman's other design feature opinions (namely, that the base lock feature and the Kinectiv trunnion's surface topography contributed to the defective design) are also inadmissible. First, Truman effectively withdrew her base lock opinion during the following exchange: "Q: Given the conflicting studies on tip-lock versus BaseLok [sic], can you say to a reasonable degree of scientific certainty that BaseLok [sic] is defective at any taper mismatch? A: No." Truman Dep. Tr. 197:18–22. Second, Truman testified that topography by itself is not the defect, but that her design defect opinion depends on the existence of a mismatch. *Id.* at 311:21–312:23. Again, because virtually all devices will have some level of mismatch, the relevant question is: "what level of mismatch produces an unreasonable risk of MACC?" Because Truman has not explained what level of mismatch produces an unreasonable risk of MACC, her dependent opinion that the Kinectiv's surface topography can increase the risk of MACC when combined with an unspecified level of mismatch is unhelpful to the jury, and thus inadmissible. *See* Fed. R. Evid. 702(a)–(b).

Finally, Truman's proposed alternative design opinions are inadmissible because they are not helpful to the jury, and Truman did not reliably apply her methods to the underlying data. To be helpful, the opinion needs to explain whether the proposed alternative is technologically and economically feasible. *See Nepanuseno v. Hansen*, 104 P.3d 984, 988 (Idaho Ct. App. 2004). By identifying other manufacturers who are using some of these options, Truman supported her opinion that options such as ceramic heads and coated tapers are technologically feasible.

Truman Report 13–16, 82–83. But Truman considered only one risk—the risk of corrosion—without weighing other risks that her proposed alternatives could introduce or exacerbate (such as the risk of fracture, which, with a ceramic head, can produce ceramic shards that harm the patient). Truman Report 18–19, 24; 82–83; Truman Dep. Tr. 225:12–227:21. Truman also admitted that her proposed alternatives could still experience corrosion (e.g., coated stems could cause greater corrosion if the coating becomes damaged, which has been known to occur). Truman Report 6 n.D; Truman Dep. Tr. 303:13–306:1. And Truman lacks data showing that nitrided tapers, ceramic heads, or ceramicized metal heads perform better in the long run than the components at issue in this litigation. Truman Dep. Tr. 306:2–13, 309:22–311:15, 314:11–316:3. Additionally, Truman did not specify whether the total benefits outweighed the costs of those options, so that a jury could conclude they were feasible alternatives in 2011, when Nutting underwent her right THR surgery. *See, e.g.*, Truman Dep. Tr. 225:12–227:21 (discussing the "increased cost with the ceramic" ten years ago). Accordingly, "there is simply too great an analytical gap between the data" Truman considered and her opinion that these alternatives were both safer and feasible. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.").

## III. Zimmer's Motion for Summary Judgment

### A. Summary Judgment Standard

Zimmer also moves for summary judgment on all three of Nutting's remaining claims. Summary judgment is appropriate where "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P.

56(a). A fact is material if, under the substantive law, it "might affect the outcome of the suit." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A dispute is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.*

In ruling on a motion for summary judgment, the court must resolve all ambiguities and draw all inferences in the non-movant's favor. *Doro v. Sheet Metal Workers' Int'l Assn.*, 498 F.3d 152, 155 (2d Cir. 2007). The court is "not 'to weigh the evidence and determine the truth of the matter[,] but to determine whether there is a genuine issue for trial.'" *Cioffi v. Averill Park Cent. Sch. Dist. Bd. of Educ.*, 444 F.3d 158, 162 (2d Cir. 2006) (quoting *Anderson*, 477 U.S. at 249). The court must enter summary judgment "after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). In those circumstances, "there can be 'no genuine issue as to any material fact,' since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." *Id.* at 323.

**B. The Court Grants Summary Judgment on Nutting's Design Defect Claim**

The Court grants Zimmer summary judgment on Nutting's design defect claim because she lacks evidence sufficient to create a genuine issue of fact regarding the existence of a defect in her Device. Without Truman's testimony, Nutting cannot identify a specific defect in her Device, and because corrosion is a known risk of using metal hip implants, Nutting cannot proceed under the malfunction theory of defect.

Plaintiffs' orthopedic surgery expert, Dr. Richard Iorio, opines that (1) Nutting suffered an adverse local tissue reaction ("ALTR"), and (2) MACC caused the ALTR.[17] But, importantly, he does not opine that a specific defect caused the MACC. He instead testifies generally that "the M/L Taper design is defective because it results in clinical failure for my patients with trunnionosis leading to ALTR," and that the cause of corrosion "was the head[-]trunnion interaction." Decl. of Peter Meyer Supp. Mot. Summ. J. Ex. I, Iorio Dep. Tr. 91:3–20, 102:16–20; *see also id.* at 111:6–9 ("And looking at the revision work, all [Dr. Meier] did was change the head, and [Nutting] got better. So I think it is safe to assume that the head-neck interaction was the problem."); Decl. of Peter Meyer Supp. Mot. Seal Ex. A, Unredacted Expert Report of Dr. Iorio at ¶ 378, ECF No. 370–1 ("Iorio Report") ("The M/L Taper with Kinectiv Technology and VerSys device implanted into Ms. Nutting on March 15, 2011 created an unreasonable risk of harm to her and was a substantial contributing factor to the premature failure of her right THR."); Decl. of Peter Meyer Supp. Mot. Exclude Test. of Dr. Iorio Ex. F, Rebuttal Expert Report of Dr. Iorio at ¶ 15, ECF No. 373–6 ("The objective evidence in this case, however, supports Dr. Meier's and my conclusion that ALTR due to MACC/trunnionosis was the most likely cause for Ms. Nutting's pain, which resolved following removal of the cobalt[-]generating femoral head.") (internal citation omitted). In sum, Dr. Iorio's opinion is that something went wrong with Nutting's Device, and Plaintiffs argue that a jury may infer the existence of a defect, and that the defect caused Nutting's injuries, from the circumstantial evidence that Dr. Iorio and Dr. Meier raise (such as the fact that Nutting's pain resolved after Dr.

[17] Zimmer contests both of these conclusions and seeks to exclude Dr. Iorio's testimony concerning them. *See generally* Zimmer's Mem. Supp. Mot. Exclude Test. of Dr. Iorio, ECF No. 372. But the Court need not resolve that motion, because even if Nutting did suffer MACC-induced ALTR, her design defect claim fails because she cannot prove the existence of a defect that caused the MACC.

Meier replaced her +0 VerSys head with a Biolox ceramic head during her revision surgery (Iorio Report ¶¶ 361–66, 387)). Thus, Plaintiffs seek to evade summary judgment by proceeding under the malfunction theory of design defect. *See* Pls.' Opp'n Mot. Summ. J. 12–15, ECF No. 433.

But to make out a prima facie case under the malfunction theory, "the product at issue must be of a type which permits a jury to infer that an injury would not have occurred had there not been a defect attributable to the manufacturer." *Black*, 488 P.3d at 1288 (citing *Farmer*, 553 P.2d at 1313). Where, as here, the plaintiff suffers "the precise type of injury that is known to result from" using the product, "th[at] fact precludes a jury from inferring that 'an injury would not have occurred . . . had there not been a defect attributable to the manufacturer.'" *Id.* (quoting *Farmer*, 553 P.2d at 1313) (first alteration added). In such circumstances, the Court need not address the further issues of abnormal use and reasonable secondary causes (such as surgical and patient factors that could have caused corrosion and ALTR (*see* Pls' SOF 30–34, 77–82)). *Id.*

Taper corrosion is a known risk of using metal hip implants, so a jury could not infer that it would not have occurred absent a defect. As discussed above, Truman testified that all tapers corrode to a certain extent, and that all modular hip devices are susceptible to corrosion at the head-neck taper junction. Truman further testified that all metal implants will corrode to some degree in the human body as long as they are touching fluid, and that fluid is always present in the hip joint, indicating that corrosion is always a risk. Dr. Meier also testified that corrosion can be present in a well-functioning hip. Further, the +0 VerSys head IFU and the Kinectiv IFU both warn of "Corrosion of metal implants," inflammatory reactions, and metal sensitivity among the adverse effects that have been reported with Nutting's Device. Pls.' SOF 84–86. Thus, because taper corrosion is a known risk associated with the use of Nutting's Device, a jury could not infer

that corrosion and reaction to the corrosion would not have occurred absent a defect attributable to Zimmer, and Plaintiffs cannot use the malfunction theory to prove the existence of a design defect. *See Black*, 488 P.3d at 1288.

Plaintiffs have no evidence of a specific design defect, and they cannot rely on the malfunction theory to imply the existence of a defect. Accordingly, the Court grants Zimmer summary judgment on Nutting's strict liability design defect claim, and on her negligence claim to the extent that it is based on a design defect.

**C. The Court Grants Summary Judgment on Nutting's Failure to Warn Claim**

Zimmer argues that its duty to warn ran to Nutting's implanting surgeon, Dr. Meier, rather than to Nutting herself. Zimmer's Mem. Supp. Mot. Summ. J. 17–18; Zimmer's Reply Supp. Mot. Summ. J. 12, ECF No. 461. Idaho recognizes the learned intermediary doctrine, under which "in some circumstances a supplier positioned on the commercial chain remote from the ultimate consumer may fulfill its duty to warn by adequately warning an intermediary." *Sliman v. Aluminum Co. of Am.*, 731 P.2d 1267, 1270–71 (Idaho 1986). For instance, "when a drug manufacturer properly warns a prescribing physician of the dangerous propensities of its product[,] . . . [t]he doctor stands as a learned intermediary between the manufacturer and the ultimate consumer." *Id.* at 1271 (quoting *Alm v. Aluminum Co. of Am.*, 717 S.W.2d 588, 591–92 (Tex. 1986)) (first and third alterations added). That is because "[g]enerally, only the doctor could understand the propensities and dangers involved in the use of a given drug." *Id.* (quoting *Alm*, 717 S.W.2d at 591–92). This rationale is even stronger in the case of a surgical implant, which is not sold directly to the general public but instead is available (and useable) only through a physician. *See, e.g.*, *Fane v. Zimmer, Inc.*, 927 F.2d 124, 129 (2d Cir. 1991) ("In this action, the key-free device is not available to the public, but rather is available only by prescription and

thus, pursuant to 21 C.F.R. § 801.109, information is disseminated to physicians and the medical community rather than to the patient directly."); *In re Zimmer NexGen Knee Implant Prods. Liab. Litig.*, 884 F.3d 746, 751–52 (7th Cir. 2018) ("The justification for adopting the learned-intermediary doctrine in cases involving prescription drugs applies even more forcefully in cases involving surgical implants. As one district judge has explained, patients 'could conceivably gain access to prescription drugs without their doctor's assistance, [but] it is not reasonably conceivable that an individual could obtain and implant a device that requires a trained surgeon without the intervention of a physician.'" (citing *Beale v. Biomet, Inc.*, 492 F.Supp.2d 1360, 1368 (S.D. Fla. 2007) (alteration in original)).

Plaintiffs do not dispute Idaho's acceptance of the learned intermediary doctrine, nor argue that it does not apply in the context of medical devices. *See* Pls.' Opp'n Mot. Summ. J. 23–30. Instead, Plaintiffs argue (correctly) that Idaho law requires "in every circumstance [that] the reliance on the intermediary must be reasonable." *Id.* at 28 (quoting *Sliman*, 731 P.2d at 1272). Plaintiffs are also correct that the reasonableness of a manufacturer's reliance on an intermediary to pass on a warning to the end user is "for the jury to determine." *Id.* (quoting *Sliman*, 731 P.2d at 1272). But the record evidence shows that Zimmer's reliance on Dr. Meier was reasonable, and Plaintiffs have not cited any evidence suggesting otherwise. *See id.* at 24–25; Zimmer's Mem. Supp. Mot. Summ. J. 17–18; Zimmer's Reply Supp. Mot. Summ. J. 12.

Zimmer represents that the VerSys and Kinectiv are "available only by prescription to be used by licensed physicians for the treatment of certain orthopaedic diseases." Zimmer's Mem. Supp. Mot. Summ. J. 17. Pursuant to federal regulations (codified at 21 C.F.R. § 801 *et seq.*), Zimmer places its warnings, intended for surgeons, for the VerSys and the Kinectiv in "a package insert that contains Instructions for Use (IFU) for each product." Pls.' SOF 82–84; *see*

*also Kline v. Zimmer Holdings, Inc.*, No. 13–513, 2015 WL 4077495, at *6, *13 (W.D. Pa. July 6, 2015) (describing how 21 C.F.R. §§ 801.5 and 801.109(c) require Zimmer to include labeling with the Kinectiv that indicates, *inter alia*, the product's effects and any relevant hazards and precautions, and to place warnings and other information "'on or within the package' from which a prescription medical device is dispensed"); Zimmer's Mem. Supp. of Mot. Summ. J. 19; Decl. of Peter Meyer Supp. Mot. Summ. J. Ex. L, Kinectiv IFU; Decl. of Peter Meyer Supp. Mot. Summ. J. Ex. M, VerSys IFU.

Because the prescription surgical implants at issue here are sold directly to surgeons and can be used only by surgeons, it is reasonable for Zimmer to warn the surgeon of the product's risks, rather than the patient, who can access and use the implant only through the surgeon. *See In re Zimmer NexGen Knee Implant Prods. Liab. Litig.*, 884 F.3d at 752. The surgeon is able to understand the risks and benefits of a given device in light of the patient's needs, and is in a better position than the manufacturer to convey those risks to the patient. *Cf. Adams v. United States*, 622 F. Supp. 2d 996, 1007 (D. Idaho 2009) ("[A] doctor may stand as a learned intermediary between a drug maker and the patient because a doctor understands the risks of the drug and is better-positioned to warn the patient."). And that is clear from the facts of this case: Nutting never communicated with Zimmer, nor had she even heard of Zimmer, prior to her right THR surgery; she did not read or rely upon Zimmer's documents "in making her decision to have the Zimmer Device implanted," but instead she received information about the Device and the surgery from Dr. Meier, whose medical judgment she trusted and relied upon. Pls.' SOF 104–106. Accordingly, the learned intermediary doctrine applies here, and Zimmer's duty to warn ran to Dr. Meier rather than to Nutting directly. *See Leavitt v. Ethicon, Inc.*, — F. Supp. 3d —, No. 20-cv-00176, 2021 WL 872696, at *6 (D. Vt. Mar. 9, 2021) ("The court predicts that the

Vermont Supreme Court would find the Restatement's rationale persuasive especially where, as here, a plaintiff claims she relied exclusively on her physician's warnings regarding the risks and benefits of TVT implantation.").

Plaintiffs dispute that the IFUs were included with Nutting's Device, but do not point to any evidence that they were not included. Pls.' SOF 83–84. Zimmer represents that it includes these IFUs with all VerSys and Kinectiv products because the FDA requires it to do so. *See* Zimmer's Mem. Supp. Mot. Summ. J. 19; Pls.' SOF 82–84. Plaintiffs bear the burden of proving that Zimmer's warnings were inadequate, which would include a theory that they were inadequate because Zimmer failed to include the IFUs with the products. If there is no evidence either way, the tie goes to Zimmer. Although it is possible that the FDA-mandated IFUs were not included with Nutting's Device, that possibility does not create a genuine dispute of material fact. *See Russell v. Ethicon, Inc.*, No. 20-CV-00405, 2020 WL 5993774, at *6 (M.D. Pa. Oct. 9, 2020) (holding that doctor's inability to remember whether he read IFU did not preclude the possibility that he read it, but was insufficient to create a genuine dispute as to whether the doctor read the IFU).

The parties fiercely dispute whether Zimmer's warnings were adequate. *See* Zimmer's Mem. Supp. Mot. Summ. J. 18–21; Zimmer's Reply Supp. Mot. Summ. J. 12–13; Pls.' Opp'n Mot. Summ. J. 25–30. But the issue of adequacy is irrelevant to this summary judgment motion, because Plaintiffs cannot establish that any alleged inadequacy in the IFUs proximately caused Nutting's injuries. *See Fitzsimmons v. Biomet Orthopedics, Inc.*, No. 19-cv-182-FtM-29NPM, 2021 WL 211267, at *4 (M.D. Fla. Jan. 21, 2021) ("Biomet argues plaintiff's failure to warn claims fail as a matter of law because (1) the M2a Magnum's instructions-for-use are adequate, and (2) plaintiff cannot establish that any alleged failure to warn proximately caused his injuries.

Because the Court agrees with the latter argument, it need not address the former." (internal citation omitted)). Dr. Meier did not read the IFUs for Nutting's Device prior to her right THR surgery. Pls.' SOF 90–92.[18] Because Dr. Meier never read the IFUs until his deposition, he would not have seen whatever warnings Zimmer put there, even if they contained everything that Plaintiffs argue is necessary for an adequate warning. Accordingly, Plaintiffs cannot prove that Dr. Meier would have chosen a different device had he been adequately warned, because he did not read the IFUs through which the warnings would have been communicated. Many courts have concluded that a plaintiff cannot establish proximate cause in these circumstances. *See, e.g.*, *Fitzsimmons*, 2021 WL 211267, at *5; *Russell*, 2020 WL 5993774, at *6 ("[I]f the physician does not read the warnings provided, the failure to provide an additional warning cannot be the proximate cause of an injury, because even if said additional warning had been provided, the doctor, having failed to review the warning in the first place, would be unaware."); *Kline*, 2015 WL 4077495, at *25 ("Dr. Sotereanos testified that he did not read the package insert before implanting the hip replacement in Mr. Kline. In fact, Dr. Sotereanos *never* reads package inserts, which have warnings on them. Thus, even if the warning in this case were insufficient, it would not have made a difference."); *In re Zimmer NexGen Knee Implant Prods. Liab. Litig.*, 218 F. Supp. 3d 700, 728 (N.D. Ill. 2016); *Leavitt*, 2021 WL 872696, at *8 ("[N]o rational fact finder could conclude [the surgeon] relied on an IFU that she cannot confirm she even read."); *In re C.R. Bard, Inc.*, MDL No. 2187, No.11-cv-00114, 2013 WL 2949033, at *3 ("In short, there is a

[18] Plaintiffs argue that there is a genuine dispute over whether Dr. Meier read the IFUs, but the transcript citations they provide do not support their argument. *See* Pls.' Opp'n Mot. Summ. J. 28; Pls.' SOF 89–92. The undisputed facts are that Dr. Meier initially testified that he did read the IFUs, but once Zimmer showed him the IFUs, Dr. Meier retracted his initial testimony by stating that he did not read the IFUs or review the package inserts. Thus, there is no genuine dispute on this point.

vast body of case law among many jurisdictions holding that there is no proximate cause where a warning—albeit ostensibly inadequate—was never read.").

Plaintiffs argue that Zimmer actively undermined any warnings contained in the IFUs. Pls.' Opp'n Mot. Summ. J. 26–27. Specifically, Plaintiffs attach to their opposition brief two Zimmer Kinectiv advertisements which, they argue, undermined the IFUs' warnings of corrosion by "advertising that the M/L Taper with Kinectiv Technology when paired with the VerSy[s] Femoral Head was designed specifically not to corrode." *Id.* at 26–27. Zimmer counters that these advertisements ran in a medical journal *after* Nutting's 2011 surgery, which is evidenced by the 2012 copyright visible on each advertisement. Zimmer's Reply Supp. Mot. Summ. J. 14.

Regardless of whether Zimmer is right, the advertisements do not support Plaintiffs' position. First, they are advertisements for the Kinectiv only; neither one mentions any femoral head, and thus they do not advertise that the Kinectiv paired with a VerSys head was "designed specifically not to corrode." Pls.' Opp'n Mot. Summ. J. 26–27. Second, and more importantly, Plaintiffs do not allege (much less cite to evidence) that Dr. Meier ever encountered or relied on these advertisements. Thus, the advertisements are irrelevant.

Plaintiffs also argue that "Zimmer heavily marketed a 2009 White Paper claiming the Kinectiv device demonstrated less fretting corrosion, a conclusion based on faulty testing." Pls.' Opp'n Mot. Summ. J. 26. Plaintiffs provide no citations for this assertion, and do not explain who authored the paper, how the testing was faulty, what Zimmer specifically claimed, or how Zimmer heavily marketed it. Again, most importantly, Plaintiffs do not allege that Dr. Meier ever read this White Paper or relied upon it. Therefore, even if the Court accepted Plaintiffs' argument that these materials undermined the IFUs' warnings, rendering them inadequate, there

is no evidence that Dr. Meier ever relied upon them, and thus they do not establish a genuine issue regarding whether Zimmer's alleged failure to warn proximately caused Nutting's injuries.

To the extent that Nutting's failure to warn claim is based on allegedly improper instructions in the Kinectiv Surgical Technique, that claim also fails for lack of evidence of proximate cause. *See* Zimmer's Mem. Supp. Mot. Summ. J. 24 & n.9; Pls.' Opp'n Mot. Summ. J. 30. Dr. Meier (1) did not rely on the Kinectiv Surgical Technique, but instead testified that he learned his surgical technique as a resident, and (2) did not apply the Kinectiv Surgical Technique, but instead applied his own method during Nutting's right THR surgery (using more than one impaction stroke; testing the components' engagement by attempting to knock the head off the trunnion, rather than testing by hand). Thus, there is no evidence that the instructions in the Kinectiv Surgical Technique proximately caused Nutting's injuries, as Dr. Meier did not follow them, or that he would have followed different instructions had the Kinectiv Surgical Technique included them. *See In re Zimmer NexGen Knee Implant Prods. Liab. Litig.*, 218 F. Supp. 3d at 728.

Nutting has "a complete failure of proof concerning an essential element" of her case, namely, proximate cause. Accordingly, the Court grants Zimmer summary judgment on Nutting's strict liability failure to warn claim, and on her negligence claim to the extent that it is premised on Zimmer's alleged failure to warn. *Celotex*, 477 U.S. at 323.

## CONCLUSION

The Court GRANTS Zimmer's motion to exclude Truman's testimony, and GRANTS Zimmer summary judgment on Nutting's claims of design defect, failure to warn, and negligence. The remaining motions to exclude expert testimony are denied as moot.

The Clerk of Court is directed to close the motions at 18-md-2859, ECF numbers 366, 371, 374, 379, 383, 386, 388, and 390; at 19-cv-699, ECF numbers 46, 51, 54, 57, 60, 61, 65, and 67; and to close case number 19-cv-699.

Dated: New York, New York
August 6, 2021

SO ORDERED

HONORABLE PAUL A. CROTTY
United States District Judge

# APPENDIX

## GLOSSARY

**TERMS:**

**+0 VerSys Head** — Zimmer 36mm +0 offset cobalt-chrome VerSys Femoral Head.

**ALTR** — Adverse Local Tissue Reaction: the body's reaction to metal debris.

**ARMD** — Adverse Reaction to Metal Debris: the body's reaction to metal debris.

**Base lock** — a head-neck connection in which the neck trunnion contacts the interior of the head bore near the base of the trunnion.

**Debride** — to remove, as in removing dead tissue.

**Degree** — angle measurement.

**Fretting** — shedding of metal particles through friction.

**Head** — the ball component of the hip prosthesis that is implanted in the hip socket.

**IFU** — Instructions for Use: the manufacturer's instructions included with the product.

**Kinectiv** — Zimmer 12/14 M/L Taper Kinectiv Stem and Neck.

**MACC** — Machine-Assisted Crevice Corrosion: corrosion due in part to micromotion between hip components causing the shedding of metal particles from the components.

**Metallosis** — the stained appearance of tissue within the hip area due to metal debris.

**Micromotion** — small amounts of movement at the head-neck junction.

**Minute** — angle measurement equal to 1/60th of one degree.

**Mismatch** — the difference between the angle of the bore in the hip head and the angle of the neck.

**Neck** — the portion of the stem that connects the neck and head.

**Necrosis/Necrotic** — dead, as in dead tissue.

**Nutting's Device** — the Kinectiv and +0 VerSys Head.

**Offset** — a feature that increases the distance between the femoral head and the taper where they join together.

**Pathology** — the molecular study of tissue.

**Revise/Revision** — a surgery to correct or replace an implanted prosthesis.

**THR** — Total Hip Replacement.

**Second** — angle measurement equal to 1/60th of one minute.

**Stem** — the component of the hip prostheses that is implanted in the patient's femur.

**Taper** — the trunnion taper: the neck end of the stem (or the Kinectiv neck) where the neck and head connect.

**Tip lock** — a head-neck connection in which the neck trunnion contacts the interior of the head bore near the top of the trunnion.

**Tolerance** — the amount of deviation from target angle that a manufacturer will allow for a component to be considered within manufacturing specifications.

**Topography** — surface texture.

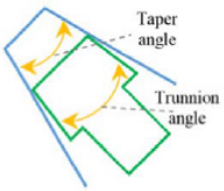
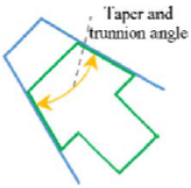
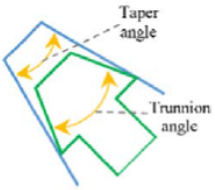
**Trunnion** — the portion of the neck designed to connect the neck to the head bore.

**Trunnionosis** — corrosion damage at the head-neck junction.

**IMAGES:**

1. **Image of +0 VerSys Head with Kinectiv (corrosion is alleged to have occurred at the junction of the components highlighted in blue):**


2. **Illustration of tip locked, matched, and base locked devices:**

| Tip locked | Matched | Base locked |
|---|---|---|
|  |  |  |